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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,148	10/31/2003	Jonathan Kagan	VALTX.001A	2819

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KNOBBE MARTENS OLSON & BEAR LLP  
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IRVINE, CA 92614

EXAMINER
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GRAY, PHILLIP A

ART UNIT	PAPER NUMBER
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3767

NOTIFICATION DATE	DELIVERY MODE
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07/09/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
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<b>Office Action Summary</b>	<b>Application No.</b> 10/698,148	<b>Applicant(s)</b> KAGAN ET AL.	
	<b>Examiner</b> Phillip Gray	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 43-50,52,54-61,72 and 73 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 43-50,52,54-61,72 and 73 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This office action is in response to applicant's communication of 3/16/2009. Currently elected amended claims 43-50, 52, 54-61 and 72-73 are pending and rejected below.

#### ***Response to Arguments***

Applicant's arguments with respect to claims 43-50, 52, 54-61 and 72-73 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 43-50, 52, 54-61 and 72-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bessler (U.S. Application Number 2004/0039452 A1) in view of Taylor (U.S. Patent 6,254,642) in further view of Moss (U.S. Patent 5,470,337).

Bessler discloses an endoscopic gastric bypass device and methods (figures 1-4). Bessler discloses a method for treating obesity with the steps of providing a gastric sleeve (figure 4) with a proximal end (42), distal end (44), and lumen extending therethrough (40), transesophageally advancing the sleeve adjacent an attachment site near the gastroesophageal junction (near 60), advancing the proximal end through the stomach and into the intestines or beyond, and attaching the proximal end at the attachment site to deliver food from the esophagus directly into the intestine (see paragraphs [0012]-[0027]). Bessler discloses a support tissue anchor tubular cuff, at the site of attachment, (42), and extending the sleeve (40) distally of duodenum or beyond (paragraph [0020]). Further Bessler discloses that the length of the tube sleeve could be up to 250cm or beyond in length [0020] and permanently attached to the cuff. The Bessler device is fully capable of being sufficiently flexible that the material traveling through the sleeve is influenced by the natural operation of the pylorus.

Bessler discloses the claimed invention except for the attaching tissue anchors configured to have a transversely reduced configuration for passing transmurally through the attachment site, and a transversely enlarged configuration after passing

transmurally through the attachment site wherein the distal end of the tissue anchor includes a proximally facing surface which rests against a serosal surface. Taylor teaches that it is known to use attaching tissue anchors configured to have a transversely reduced configuration for passing transmurally through the attachment site, and a transversely enlarged configuration after passing transmurally through the attachment site wherein the distal end of the tissue anchor includes a proximally facing surface which rests against a serosal surface, (as set forth in paragraphs at columns 7-9, and shown in figures 6a-6E) to provide an efficient low profile anchoring system with a size that resists cutting or tearing of tissue. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Bessler with a transversally reduced/enlarged configured tissue anchors wherein the distal end of the tissue anchor includes a proximally facing surface which rests against a serosal surface as taught by Taylor, since such a modification would provide the method with a transversally reduced/enlarged configured tissue anchors wherein the distal end of the tissue anchor includes a proximally facing surface which rests against a serosal surface for providing an efficient low profile anchoring system with a size that resists cutting or tearing of tissue (column 11 lines 14-25). Concerning the claim language of "without creating a serosal to serosal bond" it is examiners position that the type of attachment depicted in figures 6a-6e would not create a serosal to serosal bond.

Moss teaches surgical fasteners for securing a hollow organ or device to an outer tissue layer with a first and second opposing fastener heads which change from a

transversely reduced configuration while passing transmurally through a site to a transversely enlarged configuration after passing through the site and further wherein the enlarged configuration of the tissue anchor is transversely larger than any transverse portion of the tissue anchor when the tissue anchor is passing transmurally through the attachment site in a reduced configuration (see figures 3, 4, and 7).

Bessler in view of Taylor discloses the claimed invention except for the specific fastening anchors which transversally are reduced while passing and transversally enlarged after. Moss teaches that it is known to use specific fastening anchors which transversally are reduced while passing and transversally enlarged after as set forth in paragraphs at columns 3-6 to provide a means for tissue anchoring which substantially eliminates ancillary tissue damage and inaccurate placement. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Bessler in view of Taylor with specific fastening anchors which transversally are reduced while passing and transversally enlarged after as taught by Moss, since such a modification would provide the method with specific fastening anchors which transversally are reduced while passing and transversally enlarged after for providing a means for tissue anchoring which substantially eliminates ancillary tissue damage and inaccurate placement.

Claims 43-50, 52, 54-61 and 72-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gannoe et al. (U.S. Application Number 2004/0082963 A1) in view of Taylor (U.S. Patent 6,254,642) in further view of Moss (U.S. Patent 5,470,337).

Gannoe discloses a method and device for use in endoscopic organ procedures. Gannoe discloses a method for treating obesity and providing a lengthy sleeve and support tissue anchor with a temp or permanent cuff by suture transesophageally to an attachment site near the gastroesophageal junction, with a proximal and distal ends, where the distal end can extend into the intestines or beyond (See paragraph [0035]). The attachment site support may be implanted with or without the sleeve (see figure 5A-5E, specifically 5E). The Gannoe device is fully capable of being sufficiently flexible that the material traveling through the sleeve is influenced by the natural operation of the pylorus.

Gannoe discloses the claimed invention except for the attaching tissue anchors configured to have a transversely reduced configuration for passing transmurally through the attachment site, and a transversely enlarged configuration after passing transmurally through the attachment site wherein the distal end of the tissue anchor includes a proximally facing surface which rests against a serosal surface. Taylor teaches that it is known to use attaching tissue anchors configured to have a transversely reduced configuration for passing transmurally through the attachment site, and a transversely enlarged configuration after passing transmurally through the attachment site wherein the distal end of the tissue anchor includes a proximally facing surface which rests against a serosal surface, (as set forth in paragraphs at columns 7-

9, and shown in figures 6a-6E) to provide an efficient low profile anchoring system with a size that resists cutting or tearing of tissue. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Gannoe with a transversally reduced/enlarged configured tissue anchors wherein the distal end of the tissue anchor includes a proximally facing surface which rests against a serosal surface as taught by Taylor, since such a modification would provide the method with a transversally reduced/enlarged configured tissue anchors wherein the distal end of the tissue anchor includes a proximally facing surface which rests against a serosal surface for providing an efficient low profile anchoring system with a size that resists cutting or tearing of tissue (column 11 lines 14-25).

Moss teaches surgical fasteners for securing a hollow organ or device to an outer tissue layer with a first and second opposing fastener heads which change from a transversely reduced configuration while passing transmurally through a site to a transversely enlarged configuration after passing through the site and further wherein the enlarged configuration of the tissue anchor is transversely larger than any transverse portion of the tissue anchor when the tissue anchor is passing transmurally through the attachment site in a reduced configuration (see figures 3, 4, and 7).

Gannoe in view of Taylor discloses the claimed invention except for the specific fastening anchors which transversally are reduced while passing and transversally enlarged after. Moss teaches that it is known to use specific fastening anchors which transversally are reduced while passing and transversally enlarged after as set forth in paragraphs at columns 3-6 to provide a means for tissue anchoring which substantially



eliminates ancillary tissue damage and inaccurate placement. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Gannoe in view of Taylor with specific fastening anchors which transversally are reduced while passing and transversally enlarged after as taught by Moss, since such a modification would provide the method with specific fastening anchors which transversally are reduced while passing and transversally enlarged after for providing a means for tissue anchoring which substantially eliminates ancillary tissue damage and inaccurate placement.

Claims 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bessler in view of Taylor in further view of Moss or Gannoe in view of Taylor in further view of Moss. Both references disclose the method claimed except for the specifics of the tissue anchor. Both Bessler in view of Taylor or Gannoe in view of Taylor discloses the claimed invention except for transmurally implanting a "T-tag" to attach the cuff. It would have been obvious to one having ordinary skill in the art at the time the invention was made to transmurally implanting a "T-tag" to attach a cuff, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). The use of the "T-tag" is simply a preferred type of fastener, Gannoe specifically teaches using staples or sutures to attach to a site. It would have been obvious to use a "T-tag" as a preferred type of fastener to securely attach the cuff to the site.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to [redacted] whose telephone number is (571)272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3767

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phillip Gray/  
Examiner, Art Unit 3767

/Kevin C. Sirmons/  
Supervisory Patent Examiner, Art Unit 3767